

JUL 23 2004

K041695

## SUMMARY OF SAFETY AND EFFECTIVENESS

1. Device Name: Magnetic Resonance Imaging Accessory
2. Proprietary Name: Liberty 9000 8-ch Breast Coil with Disposable Biopsy Plate
3. Classification: Class II
4. Establishment Registration #: 1529041
5. Manufacture Facility Location: USA Instruments, Inc.,  
1515 Danner Drive  
Aurora, Ohio 44202, USA  
Telephone: 330-562-1000; Fax: 330-562-1422
6. Performance Standard: No applicable performance standards have been issued under Section 514 of the Food, Drug and Cosmetic Act.
7. Intended Use: The Liberty 9000 8-ch Breast Coil with Disposable Biopsy Plate is a receive-only RF coil, used for obtaining MR images of the breast and axillary tissue. The biopsy plates allow access to the breast anatomy during biopsy procedures. No biopsy needles are included with, or packaged with the Liberty 9000 8-ch Breast Coil with Disposable Biopsy Plate. The Liberty 9000 8-ch Breast Coil with Disposable Biopsy Plate is designed for use with the Excite 1.5T system, manufactured by General Electric Healthcare.
8. Device Description: The Liberty 9000 8-ch Breast Coil with Disposable Biopsy Plate is a phased array, receive-only MRI coil. The coil consists of a main supporting base with a coil chamber in the middle section. A sternum bridge and two lateral wings divide the chamber into two segments, one to receive each breast. Each of the hollow coil segments houses four coil elements that are insulated from the patient by a ridged plastic housing. The coil housing is made of plastic materials, which are fire rated and have high impact and tensile strength. The Liberty 9000 8-ch Breast Coil with Disposable Biopsy Plate is designed to offer optimized imaging capabilities and maximum lateral access to each breast for biopsy procedures.

## 9. Safety and Effectiveness

<b>Liberty 9000 8-ch Breast Coil Product Features</b>	<b>Comparison to predicate device or other 510(k) cleared products</b>
<b>Intended Use:</b> Breast Imaging for diagnostic purposes. The coil has a biopsy plate that allows access to the breast.	-Similar to Liberty 9000 Breast Coil with Disposable Biopsy Plate manufactured by USA Instruments, Inc. (K001582) -Similar to OBC-300 Breast Array Coil manufactured by MRI Devices, Inc. (K993776) -Similar to the Biopsy Plate included in the MR Guided Procedures (MRGP) Basic Package manufactured by Picker International Inc. (K983342)
<b>Indications for Use:</b> Identical to routine MRI imaging.	-Similar to Liberty 9000 Breast Coil with Disposable Biopsy Plate manufactured by USA Instruments, Inc. (K001582)
<b>Coil Enclosure Material:</b> FR Polyurethane Plastic, FR Royalite™ R59 ABS/PVC, FR Acetyl Plastic, FR Polycarbonate, and FR Fiberglass	-Similar to Liberty 9000 Breast Coil with Disposable Biopsy Plate (K001582), Spirit III TotalSENSE Cardiac Coil (K031172), and the Premier 7000 Phased Array CTL Spine Coil (K980157) manufactured by USA Instruments, Inc.
<b>Coil Design:</b> Phased Array, Receive-Only Coil	-Similar to Liberty 9000 Breast Coil with Disposable Biopsy Plate manufactured by USA Instruments, Inc. (K001582)
<b>Decoupling:</b> RF Chokes with Switching Diodes	-Similar to Liberty 9000 Breast Coil with Disposable Biopsy Plate manufactured by USA Instruments, Inc. (K001582)
<b>Prevention of RF Burns:</b> Does not transmit RF power; decoupling isolates the coil elements from RF fields during RF transmission; coil elements and circuitry are enclosed in a non-conductive housing.	-Similar to Liberty 9000 Breast Coil with Disposable Biopsy Plate manufactured by USA Instruments, Inc. (K001582)
<b>Radio Frequency Absorption:</b> Coil is a receive-only coil and does not transmit RF power; power deposition during imaging is limited by SAR algorithm.	-Similar to Liberty 9000 Breast Coil with Disposable Biopsy Plate manufactured by USA Instruments, Inc. (K001582)
<b>Formation of Resonant Loop:</b> Decoupling isolates the coil elements from RF fields during RF transmission; length of cable and stiffness does not permit looping.	-Similar to Liberty 9000 Breast Coil with Disposable Biopsy Plate manufactured by USA Instruments, Inc. (K001582)



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**JUL 23 2004**

Mr. James Wrenn  
Manager, QA and Regulatory  
USA Instruments, Inc.  
1515 Danner Drive  
AURORA OH 44202

Re: K041695  
Trade/Device Name: Liberty 9000 8-ch Breast Coil  
with Disposable Biopsy Plate  
Regulation Number: 21 CFR 892.1000  
Regulation Name: Magnetic resonance  
diagnostic device  
Regulatory Class: II  
Product Code: 90 LNH  
Dated: June 16, 2004  
Received: June 23, 2004

Dear Mr. Wrenn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

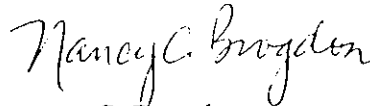
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): ~~4~~ K041695

**Device Name:** Liberty 9000 8-ch Breast Coil with Disposable Biopsy Plate

**Indications for Use:** The Liberty 9000 8-ch Breast Coil with Disposable Biopsy Plate is designed to provide Magnetic Resonance Images of the breast anatomy. The Liberty 9000 8-ch Breast Coil with Disposable Biopsy Plate is designed for use with the GE MR's Signa Excite 1.5T MRI scanner.

Anatomic Regions: Breast anatomy  
Nuclei Excited: Hydrogen

The indications for use are the same as for standard imaging:

The Signa Excite 1.5T system is indicated for use as an NMR device that produces images that: (1) correspond to the distribution of protons exhibiting NMR signal, (2) depend upon NMR parameters (proton density, spin lattice relaxation time T1, spin-spin relaxation time T2) and (3) display the soft tissue structure of the head and whole body. When interpreted by a trained physician, these images yield information that can be useful in the determination of a diagnosis.

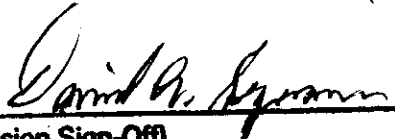
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐  
(Optional Format 1-2-96)

  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K041695